Citation:

Stamler J, Liu K, Ruth KJ, Pryer J, Greenland P. Eight-year blood pressure change in middle-aged men: Relationship to multiple nutrients. *Hypertension*. 2002 May; 39 (5): 1,000-1,006.

PubMed ID: 12019283

Study Design:

Prospective cohort study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the relationships of nutrients, alcohol intake and change in weight to change in blood pressure (BP) over eight years in 1,714 employed middle-aged men from the Chicago Western Electric Study.

Inclusion Criteria:

Male employees, age 40 to 55 years, working for at least two years at the Hawthorne Works of the Western Electric (WE) Company in Chicago, IL.

Exclusion Criteria:

- Missing one or both dietary assessments (189 men)
- Missing baseline BP (19 men)
- Missing data on education (107 men)
- Additionally, 78 men with only one or two of the possible seven annual examinations from 1960 through 1966 (examinations three to nine) were excluded.

Description of Study Protocol:

Recruitment

- In 1957, 3,102 men were randomly selected from 5,397 male employees. 2,080 (67.1%) agreed to participate
- Another 27 men served as a pilot group, totaling 2,107 men.

Design

- Dietary data were obtained at initial and second examinations one year apart (1957-1958

and 1958-1959)
- Men continuing to participate in the study were re-examined annually through 1966 (i.e, for seven years after the two dietary surveys). These examinations included measurement of serum cholesterol, a medical history and physical examination, ECG and other assessments, including BP.

Dietary Intake/Dietary Assessment Methodology

- Dietary data were obtained by two nutritionists who used standardized interviews and questionnaires based on Burke's diet history method. The dietary interview, lasting about one hour, asked about usual eating pattern on a typical workday and weekend, special diets followed now and previously, and changes in eating habits during the preceding 20 years
- This was followed by completion of a questionnaire with 195 specific food items to determine number of times in the previous 28 days each food item had been eaten and quantity per serving
- Supplementary information regarding food preparation was obtained from a questionnaire mailed to wives and returned by participants at interview. Information on food preparation was also obtained from neighborhood restaurants and bakeries
- When a man reported habitual consumption of a dish not on the list of 195 foods, the recipe was obtained and analyzed into its component parts for nutrient assessment.

Blinding Used

Not applicable.

Intervention

Not applicable.

Statistical Analysis

- The Generalized Estimating Equation (GEE) method for longitudinal data was used to estimate relationship of baseline dietary factors to average change in SBP and DBP per year, with adjustment for possible confounders
- The relationship of each individual nutrient to BP change was assessed by the coefficient of the cross-product (interaction) term between the nutrient and a time variable, T (T= zero, one, two, three, four, five, six, seven and eight). The model also included the time T, the nutrient variable, baseline age, height, education, smoking, alcohol (more than two drinks per day), age x T, height x T, education x T, smoking x T, alcohol x T, and change in weight during follow-up
- Based on findings in analyses on individual dietary variables and BP change, GEE analyses were done with multiple baseline dietary factors as independent variables, with adjustment for possible confounders
- No multivariate analysis included two variables that were part-and-whole (e.g., animal protein and total protein).

Data Collection Summary:

Timing of Measurements

- Dietary data were obtained at initial and second examinations one year apart (1957-1958 and 1958-1959)

- Men continuing to participate in the study were re-examined annually through 1966 (i.e., for seven years after the two dietary surveys at the first and second examination).

Dependent Variables

- BP was measured by study physicians by use of standard mercury manometers, with men seated in a quiet room, after a five-minute rest
- Korotkoff phase 1 and 5 were used for SBP and DBP pressure, respectively.

Independent Variables

- Total, animal protein and vegetable protein; total fat, saturated fat, monounsaturated fat, and polyunsaturated fatty acids; total carbohydrate; cholesterol
- Keys dietary lipid score; calcium; alcohol; vitamin C, beta-carotene and antioxidant index; average annual change in weight.

Control Variables

- Time
- Baseline age
- Education
- Height
- Alcohol use (more than two drinks per day)
- Cigarette use (no, yes)
- Change in weight.

Description of Actual Data Sample:

- *Initial N:* 2,107 men
- *Attrition (final N):* 1,714 men
- *Age:* 47.6±4.4 years
- *Ethnicity:* Not reported
- *Other relevant demographics:*
  - Average baseline SBP (134.9mmHg) and DBP (87.1 mmHg) were at high-normal levels
  - 56% were smokers
  - 86% consumed alcohol (17% drank at least two drinks per day)
  - Animal and vegetable protein intake were 11.5% and 3.5% of calories, respectively
- *Anthropometrics:* Baseline BMI=25.5±3.2kg/m^2
- *Location:* Chicago, IL.

Summary of Results:

Variable	Regression Coefficient (Z-Score) SBP Change/Y, mmHg	Regression Coefficient (Z-Score) DBP Change/Y, mmHg
Animal protein, %kcal	0.0567 (2.35)	-0.0022 (-0.16)

Vegetable protein, %kcal	-0.2445 (-2.91)	-0.1353 (-2.80)

Other Findings

In analyses of individual dietary variables:

- SBP: There were positive relationships of baseline intakes of total protein, animal protein, total fat, SFAs and monounsaturated fatty acids, cholesterol, Keys dietary lipid score, calcium and heavy alcohol intake to average annual SBP change from baseline; post-baseline average annual change in weight was strongly related to SBP change. There were inverse relationships of baseline vegetable protein, total carbohydrate, beta-carotene, and antioxidant index to average annual SBP change
- DBP: There were positive relationships of baseline total fat, saturates, monounsaturates, polyunsaturates, Keys score and average annual weight change from baseline to average annual DBP change. There were inverse relationships of baseline vegetable protein, vitamin C, beta-carotene, and antioxidant index to average annual DBP change
- In analyses of combinations of dietary factors, cholesterol, Keys score and alcohol were positively related to change in SBP (e.g., Z-scores 2.21, 2.05 and 2.50); vegetable protein and antioxidant index were inversely related to change in systolic and diastolic pressure. Change in weight was directly related to change in systolic and diastolic pressure.

Author Conclusion:

The authors concluded that:

- Their findings support the concept that multiple macro- and micronutrients, alcohol intake and calorie imbalance relate prospectively to blood pressure change
- Independent relationships to average annual change in BP of several specific nutrients assessed at baseline were observed: Dietary cholesterol and Keys dietary lipid score positively related to SBP change, vegetable protein and the antioxidant vitamin C and beta-carotene inversely related to BP change
- They could confirm that baseline level of alcohol intake and weight gain during follow-up years is positively related to BP change.

Reviewer Comments:

This study did not measure intake of salt, potassium, magnesium or fiber.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes

3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A

3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	???
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	N/A
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	N/A
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A

6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes

10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes